
FELIZ S EZ

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **FELIZ S EZ** (Escitalopram and Etizolam Tablets (5 mg and 10 mg) [Please refer the complete prescribing information for details].

Antidepressants increased the risk compared to placebo of suicidal thinking and behaviour (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro (US brand of Escitalopram) or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behaviour. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro (US brand of Escitalopram) is not approved for use in paediatric patients less than 12 years of age. [as per Warnings and Precautions: Clinical Worsening and Suicide Risk (4.4), Patient Counselling Information: Information for Patients (9), and Use in Specific Populations: Paediatric Use (4.6)].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Escitalopram* The mechanism of antidepressant action of escitalopram, the S-enantiomer of racemic citalopram, is presumed to be linked to potentiation of serotonergic activity in the central nervous system resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT). In vitro and in vivo studies in animals suggest that escitalopram is a highly selective serotonin reuptake inhibitor (SSRI) with minimal effects on norepinephrine and dopamine neuronal reuptake. Escitalopram is at least 100 fold more potent than the R-enantiomer with respect to inhibition of 5-HT reuptake and inhibition of 5-HT neuronal firing rate. Escitalopram has no or very low affinity for serotonergic (5-HT₁₋₇) or other receptors including alpha- and beta-adrenergic, dopamine (D₁₋₅), histamine (H₁₋₃), muscarinic (M₁₋₅) and benzodiazepine receptors. Escitalopram also does not bind to or has low affinity for various ion channels including Na⁺, K⁺, Cl⁻ and Ca⁺⁺ channels. Antagonism of muscarinic, histaminergic, and adrenergic receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular side effects of other psychotropic drugs.

Etizolam Mainly acts on Limbic system and ascending reticular formation in the CNS and binds to BZD receptor. The binding will facilitate GABA mediated chloride channel opening and produce hyperpolarisation. This will produce an increase in the concentration of the inhibitory neurotransmitter GABA and chloride ions and decrease firing rate of neuron. These in turn alters normal function of the body.

INDICATIONS: FELIZ S EZ is indicated for depression, obsessive-compulsive disorder, major depressive episodes, panic disorder, anxiety disorder and insomnia.

DOSAGE AND ADMINISTRATION: As prescribed by the physician.

CONTRAINDICATION: Cases of serious reactions have been reported in patients receiving an SSRI. Escitalopram in combination with a monoamine oxidase inhibitor (MAOI) and in patients who have recently discontinued an SSRI and have been started on an MAOI. Escitalopram should not be used in combination with an MAOI. Escitalopram may be started 14 days after discontinuing treatment with an MAOI. At least 7 days should elapse after discontinuing Escitalopram treatment before starting an MAOI. Disease conditions like myasthenia gravis, acute angle-closure glaucoma, severe respiratory failure or hepatic impairment and in patients with hypersensitivity to benzodiazepine.

FELIZ S EZ is contraindicated in pregnancy and breast feeding.

WARNINGS & PRECAUTIONS: *Escitalopram* **Clinical Worsening and Suicide Risk:** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. *Screening Patients for Bipolar Disorder:* A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. *Serotonin Syndrome:* The development of a potentially life-threatening serotonin syndrome has been reported with SNRIs and SSRIs, including Escitalopram, alone but particularly with concomitant use of other serotonergic drugs. *Abnormal Bleeding:* SSRIs and SNRIs, including Escitalopram, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to the risk.

Interference with Cognitive and Motor Performance: In a study in normal volunteers, Escitalopram 10 mg/day did not produce impairment of intellectual function or psychomotor performance.

Etizolam: Caution should be exercised in patients with history of lung insufficiency, muscle weakness, impaired liver or kidney function, alcoholism or drug addiction, elderly, during pregnancy and breastfeeding. Etizolam is contraindicated in patients with increased eye pressure, coma, sleep disorder, porphyria, severe lung disease and hypersensitivity. It may cause dizziness or drowsiness, lack of attentiveness, concentration or ability of reflexive motion. Avoid driving a car or operating machinery requiring alertness.

DRUG INTERACTIONS: *Escitalopram: Triptans* There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Escitalopram with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. *CNS Drugs:* Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. *Alcohol:* Although Escitalopram did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Escitalopram is not recommended. *Cimetidine:* In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of 400 mg twice a day cimetidine for 8 days resulted in an increase in citalopram AUC. *Digoxin:* In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of citalopram and digoxin.

Etizolam Drug interactions have been reported with CNS depressants phenothiazines, barbiturates and alcohol; MAO inhibitors and Fluvoxamine maleate.

ADVERSE REACTIONS: Dry Mouth, Sweating Increased, Dizziness, Nausea, Diarrhea, Constipation, Indigestion, Abdominal Pain, Influenza-like Symptoms, Insomnia, Sinusitis, Ejaculation Disorder, Impotence

MARKETED BY:



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(Additional information is available on request)